

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference H310899PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/CA2004/000966	International filing date (<i>day/month/year</i>) 29 June 2004 (29.06.2004)	Priority date (<i>day/month/year</i>) 01 July 2003 (01.07.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant MCMASTER UNIVERSITY			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

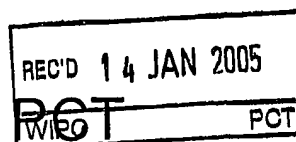
3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland		Date of issuance of this report 03 January 2006 (03.01.2006)
Facsimile No. +41 22 740 14 35		Authorized officer Athina Nickitas-Etienne
Form PCT/IB/373 (January 2004)		Telephone No. +41 22 338 89 95

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/CA2004/000966

International filing date (day/month/year)
29.06.2004

Priority date (day/month/year)
01.07.2003

International Patent Classification (IPC) or both national classification and IPC
C12Q1/34, C12Q1/42, C12Q1/48, C12Q1/44

Applicant
MCMASTER UNIVERSITY

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Pellegrini, P

Telephone No. +49 89 2399-5729



BEST AVAILABLE COPY

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000966

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☒ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

BEST AVAILABLE COPY

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000966

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 19

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 19
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

BEST AVAILABLE COPY

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000966

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2,4,6-9,11-18
	No: Claims	1,3,5,10,20,21
Inventive step (IS)	Yes: Claims	
	No: Claims	1-18,20,21
Industrial applicability (IA)	Yes: Claims	1-18,20,21
	No: Claims	

2. Citations and explanations

see separate sheet

BEST AVAILABLE COPY

Item III

1. Claim 19 is not clear (article 6 PCT), as the enzyme inhibitor is not defined by actual, concrete technical features (such as its chemical structure) which would clearly and unambiguously characterize it, but by the method of identifying said enzyme inhibitor. Such definition might well encompass known compounds irrespective of their property of being enzyme inhibitors identified by the method of the present application, and does not allow to discriminate between novel and known compounds. Furthermore, the application discloses in a clear way no enzyme inhibitors identified with the method of the present application. For these reasons, no search and no assessment of novelty and inventive step have been carried out on claim 19.

Item V

1. Reference is made to the following documents:

D1: TYAGI S ET AL: "MOLECULAR BEACONS: PROBES THAT FLUORESCCE UPON HYBRIDIZATION" NATURE BIOTECHNOLOGY, NATURE PUBLISHING, US, vol. 14, 1 March 1996, pages 303-308.

2. The subject-matter of claims 1, 3, 5, 10, 20 and 21 is not novel (article 33(2) PCT).
 - a. D1 (page 305, left column, para.4-page 307, left column, para.1), representing the closest prior art, discloses a method for monitoring DNA polymerization reaction, comprising performing the reaction in presence of a signaling aptamer (molecular beacon) specifically binding to the reaction product (amplification product), and measuring the increase in fluorescence emission. The signaling aptamer does not bind to the individual nucleotides which constitute the reaction reagents, therefore it has different affinities for reagent and product as required by claim 1. Furthermore, D1 implicitly discloses a combination of nucleotides (reaction substrates), DNA polymerase (enzyme) and signaling aptamer, i.e. the components of the kits of claims 20 and 21.

BEST AVAILABLE COPY

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/CA2004/000966

3. The subject-matter of claims 2, 4, 6-9 and 11-18 is novel (article 33(2) PCT), as the technical features of these claims are not disclosed by the cited prior art.
4. Dependent claims 2, 4 and 6-12 do not appear to be inventive: once the general concept of monitoring a chemical reaction by using signaling aptamers with different affinities for reagent and product is known, all the particular embodiments defined by such claims fall within the competence and abilities of the skilled person.
5. Claims 13-18 are also not inventive, as they derive from trivial modifications of the method of D1.

BEST AVAILABLE COPY